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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,731	10/07/2003	Karen M. Kramer	279.653US1	8277

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EXAMINER

MORALES, JON ERIC C

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/680,731

Applicant(s)

KRAMER ET AL.

Examiner

Jon-Eric C. Morales

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-18, 21-39 and 40-52 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/2007</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 10, filed 1/8/2007, with respect to restriction requirement have been fully considered and are persuasive. The restrictions of claims 1-52 have been withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 9-11, 13-17, 21, 24-26, 29-35 and 41-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Ericksen et al. (US Patent No. 6128528). Ericksen discloses an implantable pulse generator 100 coupled a lead containing multiple electrodes 28, 32, placed in the atrium and ventricle for sensing and cardioversion/defibrillation for arrhythmia and tachyarrhythmia therapy. The implantable device contains sense amplifiers 126, a A/D converter 104 (programmable sampler), a control system 102, accelerometer (physical activity sensor) 134, a memory unit that that contain registers and buffers 152, 154, 158, and a telemetry circuit 124 (Fig. 2, column 9, lines 50-53, column 10 lines 42-45, column 11 lines 15-18, column 12 lines 8-13, 23-25, 64-67, column 13 lines 16-18).

Regarding claim 2, the memory unit is hardware based containing both on chip RAM and ROM as well as off-chip SRAM and DMA (column 14 lines 6-9).

Art Unit: 3766

Concerning claims 3-5 and 30, 32, and 42 the buffer is configured to be in a first in first out basis with registers that contain the memory address, size of the buffer and the type of data to be stored. Also the registers store representation of time of when data is stored in the buffers. A history log stored as well, the buffer also includes a destination register (index) that shows where in the buffer to write data (column 6 lines 15-17 column 13 lines 16-40).

With respect to claim 11, 17, and 35, raw unfiltered activity sensor (accelerometer) signals and the filtered signals from the atrial and ventricular sense electrodes, are transferred to the buffers (column 12 lines 23-25, column 13 lines 1-7, 12-20).

Regarding claims 13, 25, 31, a table is used to correlate address of a data block that contain a certain value associated with the type of data that is being moved around between memory registers. The certain error code value (pointer) is the location that can be looked up for the specific sensed signal that was stored (column 18 lines 28-67, column 19 lines 1-2).

Concerning claim 16, the accelerometer is coupled to a rate response circuit; this circuit is in communication with the controller. The controller maintains and communicates information from the rate response circuit as well as the atrial and ventricular sense amplifiers (column 15 lines 20-27, 36-38).

With respect to claim 22, 33, and 34, the device of Ericksen includes telemetry circuitry that is in communication with the controller as well as an external programmer 400. The data is sent from the telemetry buffers and register to external device. An

Art Unit: 3766

uplink of real time atrial and ventricular EGM can be sent to the external programmer as well (Fig. 1, column 11 lines 9-14, column 12 lines 8-17, column 15 lines 4-13)

Regarding claim 26, the data is based on a first in first out priority basis (column 13 lines 19-20).

Concerning claims 37 and 38, sensed activity that is placed into memory buffers includes values from an evoked response that is received from the electrical stimulation of the defibrillation lead preceding and following arrhythmia and tachyarrhythmia detection and therapies (column 13 lines 22-27).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 3766

5. Claims 6, 8, 23, 28, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericksen et al. (US Patent No. 6128528) as applied to claims 1, 24, and 29 above, and further in view of Lee (US 2004/0167416). Ericksen discloses the invention substantially as claimed however does not show that the sensed signal determines a rate at which it is being sampled and the size of the buffer. Lee discloses that an ECG signal from a patient has a sampling rate on the order of 100 Hz. Memory needed for this type of sensed ECG requires at least a buffer capacity of 128 Kbytes. The buffer is in a looping (circular) fashion when storing the sensed ECG signal (section 0036 and 0038). The use of a circular buffer is used since the ECG is continuously being recorded at 100Hz sampling rate into a 128 Kbytes of memory allowing the continuous signal to be more discrete. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention, to modify the device of Ericksen by having the sampling rate of a electrical signal to be at 100 Hz and use a circular buffer to store the data as taught by Lee in order to facilitate that the continuous signal is able to get stored and that a discrete signal can be created from the continuous signal.

6. Claims 12 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericksen et al. (US Patent No. 6128528) as applied to claims 1 and 29 above, and further in view of Stone et al. (US patent No/ 6045513). Ericksen discloses the invention substantially as claimed however does not show that the filtered data from the accelerometer is stored into memory. Stone discloses that data from an accelerometer that is within a pacemaker is collected (stored) after it has been filtered with a bandpass filter (column 9 lines 1-7). Filtering data from the accelerometer allows for a useful, less

Art Unit: 3766

noisy, signal to be used to determine the physical activity of a patient. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ericksen et al. by adding the filtering method of the accelerometer in order to facilitate a clean, useful signal to determine the physical activity of a patient.

7. Claims 18 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericksen et al. (US Patent No. 6128528). Ericksen discloses an implantable medical device having all the features claimed except for sensing minute volume of a patient. Although the sensing of minute volume is not explicitly disclosed in the reference, it would have been obvious to have minute volume sensed from within a n implantable medical device since it is well known to one of ordinary skill in the art that minute ventilation data is recorded in implantable medical devices in order to determine lung congestion and breathing problems (i.e. Cheyne stokes breathing and apnea in CHF patients).

8. Claims 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericksen et al. (US Patent No. 6128528) as applied to claim 41 above, and further in view of Bardy (US Patent No. 6312378). Ericksen discloses the invention substantially as claimed however does not show the external device to be able to display a trend of the sensed data, being able to transfer the data to a database on a global computer network, the external device uses a wireless network connection and that the external device is connected to a global computer network. Bardy discloses that a computer (external device) communicates and receives data from the implanted device wirelessly via RF signals and can chronologically (trend) display on a screen the data so that a

Art Unit: 3766

physician maybe able to analyze the data. Also disclosed is that the computer is able to place data onto a database system via the Internet (global computer network). The computer connects to a server system via the Internet and then accesses a database to create a patient record for storage of the implanted signal data (column 5 lines 49-55, 60-67, column 6 lines 1-5, 28-67). Use of a wireless transmission of data from the implanted device to the external device removes any invasive wiring to come out of the body of a patient. Storing the data on a database connected to the Internet allows for global access an authorized personal to access patient data for emergency purposes. A good example is if a specialist is needed for an opinion but not at the hospital for questioning. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ericksen by adding the internet database and connection as well as the wireless transmission of data from the implanted device to the external device in order to facilitate global access of patient data and a non invasive method of transmitting data from an implanted device.

Allowable Subject Matter

9. Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The following patent and patent application publications are cited and further show the state of the art with respect to an implantable medical device with a plurality of

Art Unit: 3766

electrodes, sense amplifiers, a control unit a sampler and a memory to sense electrical activity in general:

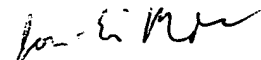
Hess; Michael F. et al.	US 5814083
Sheldon, Todd J. et al.	US 20030158492
Hartley; Jesse W. et al.	US 6076015
Powell; Richard M.	US 5549654
Amely-Velez, Jorge N.	US 20020107550
Gebhardt, Ursula et al.	US 20040225332

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is 571-272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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